

REMARKS

Rejection under 35 U.S.C. § 112, first paragraph:

Claims 7-9 and 11 are rejected under 35 U.S.C. § 112, first paragraph, on the basis that the specification is allegedly not enabling for the claimed process with respect to processes that employ released α 2,8/2,9 polysialyltransferases other than released α 2,8/2,9 polysialyltransferase from *Escherichia coli* K92. Applicant traverses this basis for rejection.

More particularly, the Examiner objects that the term “released α 2,8/2,9 polysialyltransferase” would include variants, mutations, and recombinants of *Escherichia coli* K92 that are not enabled by the specification and would require undue experimentation. The Examiner cites *In re Wands*, (8 USPQ 2nd 1400 (Fed Cir. 1988)) for the criteria for undue experimentation.

The kernel of the present invention is the “released” aspect of the α 2,8/2,9 polysialyltransferase. The present application discloses for the first time that “released” α 2,8/2,9 polysialyltransferase can be employed for synthesizing a polysialic acid product having alternating α 2,9- and α 2,8 linkages of sialic acid and that the use of such “released” α 2,8/2,9 polysialyltransferase makes the claimed process much more efficient as compared to a process that employed membrane bound α 2,8/2,9 polysialyltransferase, as employed in the prior art. The examiner admits that claim 10 is enabled with respect to the use of “released” α 2,8/2,9 polysialyltransferase from *Escherichia coli* K92. Variants, mutations, and recombinants of α 2,8/2,9 polysialyltransferase from *Escherichia coli* K92 are not required in order to practice the

invention. An Applicant can not be expected to disclose and enable every non-essential variation of the claimed process.

Withdrawal of this basis for rejection is requested.

Rejection under 35 U.S.C. § 112, first paragraph:

Claims 7-9 and 11 are rejected under 35 U.S.C. § 112, first paragraph, on the basis that the specification is allegedly not satisfy the written description requirement for the claimed process. More particularly, the written description provides only a single working example of the claimed process, i.e., the use of released α 2,8/2,9 polysialyltransferase from *Escherichia coli* K92. Applicant traverses this basis for rejection.

The written description requirement for “released α 2,8/2,9 polysialyltransferase” is supported in the specification at page 4, lines 10-19 and at page 4, lines 21-30.

Withdrawal of this basis for rejection is requested.

Rejection under 35 U.S.C. § 103(a):

Claims 7-11 are rejected under 35 U.S.C. § 103(a) as being obvious over Vann or Steenbergen or Van Dijk in combination with the common knowledge that membrane proteins may be “released” by the use of detergent. Applicant traverses this basis for rejection.

Applicant teaches that enzymatically active "released" α 2,8/2,9 polysialyltransferase may be obtained by the use of detergent in combination with a hexameric histidine tag fused at the N-terminal end of such α 2,8/2,9 polysialyltransferase. (See: Specification, page 4, lines 10-19.) There is no teaching in the present application that enzymatically active "released" α 2,8/2,9 polysialyltransferase may be obtained using detergent alone, i.e., in the absence of modification with the hexameric histidine tag or its functional equivalent. Applicant is unaware of any support that the Examiner's suggested combination would be inoperable with respect to the practice of the claimed process.

Withdrawal of this basis for rejection is requested.

Summary:

Claims 7-9 and 11 are enabled by the specification. Claims 7-9 and 11 are supported by the specification with respect to the written description requirement. Claims 7-11 are patentably unobvious over the cited prior art. Allowance of claims 7-11 is respectfully requested.

Respectfully submitted,



Donald G. Lewis
Reg. No. 28,636
The Scripps Research Institute
10550 N. Torrey Pines Road TPC-8
San Diego, CA 92037
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(858) 784-2937